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ABSTRACT

Harvard Watch asserts that withholding essential information from public scrutiny is not uncommon at Harvard University. Maintaining that Harvard has reversed its position from extolling the virtues of public disclosure to one of imposing secrecy, the document suggests that this about face is linked to the university's recent collaboration with the private sector biomedical industry. Describing a case in which a Medical School dean knew about illegal and unethical misconduct of a research fellow 5 months prior to public exposure, the document suggests Harvard officials routinely refuse the public direct access to information about corporate sponsored research agreements or to internal records of fraud, ethical misconduct, and wastefulness. Since Harvard has recently entered into research agreements with many chemical and pharmaceutical companies, Harvard Watch recommends public disclosure of: the conclusions of academic review committees and all other committees that investigate ethical misconduct; the texts of all collaborative research agreements with private sector biomedical companies; the extramural affiliations and commitments of Harvard faculty; the name of each company that sponsors Harvard research and the dollar amount of their sponsorship; the names of the principal investigators who benefit from the sponsorship; and a detailed explanation of the purpose of the research. (SM)

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Summary

1. Harvard Medical School Dean Daniel C. Tosteson knew about the illegal and unethical misconduct of Harvard research fellow, Scheffer C. G. Tseng, fully five months before the case was first exposed by the Boston Globe. Tosteson has probably had knowledge of Tseng's improprieties since 1986, but he chose not disclose this information. Nor does it appear that he or any other Harvard Administrator followed-up on the physical and psychological well-being of the hundreds of patients on whom Tseng experimented.

2. This example of withholding essential information from public scrutiny is not exceptional at Harvard, but is characteristic of the University. Harvard officials routinely and systematically refuse the public direct access to any information about corporate sponsored research agreements or to records of fraud, wastefulness and ethical misconduct uncovered by faculty review committees. University officials do this in direct contradiction to the Harvard's regulations governing disclosure.

3. Harvard's safeguards for public disclosure have steadily been weakened following the initiative of the Harvard Administration. The history of this trend is bound up with the history of corporate sponsored biomedical research at the University.

4. Currently Harvard has entered into research agreements with many chemical and pharmaceutical companies. All of them were secretly negotiated and implemented. Both the wide extent and rapid proliferation of corporate sponsored biomedical research at Harvard are startling: before 1974, Harvard

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had no formal links with the biomedical industry; by 1986, many of Harvard's faculty researchers were either consulting for or receiving research funding from the industry, and the University had entered research agreements with many major pharmaceutical and chemical companies in the country.

5. Though precise documentation is not publicly available, Harvard probably has signed research agreements with at least 32 companies and trade associations. Among them are: Council for Tobacco Research, Du Pont, Johnson and Johnson, Pharmaceutical Manufacturers Association, R.J. Reynolds, Revlon, Smokeless Tobacco Research Council, Stroh Brewery, and Union Carbide.

6. Harvard Watch recommends public disclosure of: the conclusions of academic review committees and all other committees that investigate ethical misconduct; the texts of all collaborative research agreements Harvard has entered into with private sector biomedical companies; the extramural affiliations and commitments of Harvard faculty; and the name of each company that sponsors research at Harvard, the dollar amount of their sponsorship, the names of principal investigators who benefit from the sponsorship, and a detailed explanation of the purpose of the research.

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1. Introduction

If there are two values that most characterize universities, they are the scholarly right of free inquiry and the academic ritual of unrestricted discussion and dissemination of knowledge. Harvard University occupies a unique place among universities, and serves a signal function in promoting and exercising those values. Recent scandal at a Harvard-affiliated hospital reveals that Harvard University undermines the intent of those university standards when the subject of inquiry is Harvard itself.

Scheffer C. G. Tseng was a research fellow at Harvard-affiliate, Massachusetts Eye and Ear Infirmary. Between 1984 and 1986, he illegally treated hundreds of people with an experimental ointment, misused federal research funds, and profited substantially from the appreciation of the stock he owned in the biotechnology company which produced the ointment. First the hospital and later Harvard University convened review committees to investigate Dr. Tseng. By May, 1988, they had rendered their conclusions to Medical School Dean Daniel C. Tosteson. But Tosteson did not make public the review committee reports or his personal knowledge of Tseng's improprieties. Moreover, it appears that he did not notify the National Institutes of Health, which funded Tseng's fraudulent experiments; nor is there any evidence to believe that Harvard followed-up on the physical and psychological well-being of Tseng's former patients. Only when the Boston Globe first covered the story in October, 1988, did Tosteson issue any public statement at all, and to this day, he refuses to comment further on the case.[1]

[1] Dean Tosteson published a brief statement on the Tseng case the day the Boston Globe first exposed the story. He wrote, "A serious violation of the Harvard Medical School's conflict of interest policy occurred in connection with the study at the Massachusetts Eye and Ear Infirmary... Our investigation showed that the study was conducted without adequate steps being taken to protect it from potential bias, that the research trainee was insufficiently supervised, and that timely and complete disclosures were not made by the investigators with repect to changes in the

The Tseng case is only one exposed example of a university-wide problem, however. Administrators at Harvard routinely and systematically withhold essential information from public scrutiny when occurences at Harvard are at issue. Harvard withholds records of fraud, wastefulness, and ethical wrongdoing occuring within its research laboratories and hospitals. Information documenting the name of each company that sponsors research at Harvard, and a detailed explanation of the purpose of the research is routinely kept from public review. Moreover, Harvard University has added several exemptions to its own rules and regulations governing public disclosure since 1974. The information that Harvard should, in accordance with its own regulations, provide about sponsored research is inadequate, not easily accessible and often denied the individual upon request.

Harvard's apparent about-face, from extolling the virtues of public disclosure to imposing secrecy, is closely linked to the university's recent collaboration with the private sector biomedical industry. Since the mid-seventies, Harvard has sought to capitalize on the fast-growing and lucrative biomedical technology industry, and carve an influential niche for itself in the industry's continued growth. As Harvard Vice-President and General Counsel Daniel Steiner explained to a U.S. congressional committee, "What attracted us [to industry-sponsored research]? Very simply, the apple... looked very big and shiny. The chance of very large and significant financial return to support future research at the university was there."[2] Pharmaceutical and chemical

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protocol, the scope of the study, and their financial interests." (Statement by Daniel C. Tosteson, Dean Harvard Medical School, October 19, 1988). Tosteson did not say whether he would now make those disclosures, nor did he indicate how Harvard would take an active role in exposing the Tseng case and in preventing cases like it from happening in the future.

[2] Daniel Steiner, evidence in U.S. Congress, House Committee on Science and Technology, Subcommittee on Investigations and Oversight and Subcommittee on Science Research, and Technology, *Commercialization of Academic Biomedical Research.* Hearings, 97th Congress, 1st

corporations now sponsor roughly ten percent of the research conducted at Harvard Medical School.[3] Corporate sponsored university research poses specific barriers to public disclosure that set it apart from most federally sponsored research. While the Freedom of Information Act provides the public a means by which to gather information regarding research sponsored by the federal government, the public has no comparable means to obtain equivalent information regarding corporate sponsored research.

This report documents the development and influence of the biomedical industry at the University from a case study of the Harvard-Monsanto Agreement of 1974, the accompanying legitimacy that the University places on secrecy, and the real and immediate dangers to the public posed by this secrecy. In addition, the report recommends ways in which Harvard can ensure the public access to important information regarding corporate sponsored research at the University, and thereby strengthen academic freedom and public disclosure safeguards which benefit both the community of scholars and the public at large.

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session (June 8-9, 1981), pp. 98-99. Cited in The New Politics of Science, David Dickson, University of Chicago Press, p. 80.

[3] "Financial Report to the Board of Overseers of Harvard College for 1986-1987," p. 35.

2. Corporate Sponsored Research and the Wane of Disclosure Safeguards

The weakening of Harvard's public disclosure safeguards is bound up with the history of corporate sponsored biomedical research at the University. Harvard began to apply selectively its standards of public disclosure in 1974, when it signed the first research agreement in biomedical technology between a major university and a major pharmaceutical company. In entering into the Agreement, Harvard formally agreed to withhold information from the public in certain cases and, in others, to delay its publication.

For Harvard, the Agreement with Monsanto Company of St. Louis, Missouri, was both a precedent for a new and lucrative funding arrangement and a model for subsequent agreements with other companies. As Harvard Vice-President and General Counsel Daniel Steiner told a U.S. congressional committee, the Agreement was a "pathbreaker."[4] In exchange for $23 million parceled out over twelve years, Harvard gave Monsanto special access to information and its resources, both material and human, and provided the agricultural chemical giant the results of their joint research.[5]

This access was important to Monsanto. At the time of the Agreement, Monsanto was the nation's 38th largest company, with sales amounting to $3.5 billion (making it one of the world's leading multinational corporations in agricultural chemicals.) It was testing a strategy that would enable it to expand from its petrochemical base into biotechnology. But the company lacked both the skills which Harvard could provide and the willingness to invest the money

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[4] Daniel Steiner, in testimony given at U.S. Congressional hearings, 1981.

[5] According to then-Vice President of Technology at Monsanto, Monte C. Throdahl, Monsanto deducted the $23 million from its taxes as a business expense, interview by telephone with Throdahl, March 16, 1988.

to build them for itself.[6] As part of the agreement, Monsanto scientists often worked in the laboratories it funded at Harvard. Recent interviews conducted by Harvard Watch have revealed additional, previously confidential, information: Monsanto officials were in frequent contact with Harvard scientists and administrators and to some limited extent, Harvard scientists travelled to St. Louis to work in Monsanto's laboratories. Also, Monsanto gained access to the day-to-day operations of a major university laboratory; to the labor and abilities of top university scientists, post-doctorate students, graduate and undergraduate students, and to a portion of Harvard's vast material resources, laboratory and library.

Harvard was contractually obligated to provide an atmosphere conducive to the aims of its business partner and responsive to its corporate priorities. In fact, in order to enter the Agreement, Harvard revised longstanding rules designed to uphold academic integrity and social responsibility. Harvard altered its patent policy in order to grant Monsanto exclusive licensing privileges and conceded to the chemical company the right to edit and withhold publication of papers originating from funded laboratories for up to 90 days. Today, both exclusive licensing and prepublication review rights are specified exceptions to Harvard's academic freedom and public disclosure regulations.[7]

Until 1974, the University drew a sharp distinction between the public nature of biomedical research and the potential for financial gain from royalties and profit. Harvard's patent policies are a measure of this sense of responsibility to serve the public's interest. In policy statements dating from 1934, Harvard usually dedicated patents in medicine to the government in the

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[6] Ibid.

[7] "Principles and Policies That Govern Your Research and Other Professional Activities," Faculty of Arts and Sciences, Harvard University, February, 1988.

public's interest: "No patents primarily concerned with therapeutics or public health may be taking out by any member of the University, except with the consent of the President and Fellows: nor will such patents be taken out by the University itself except in dedication to the public."[8] A quote from Jonas Salk, inventor of the polio vaccine, can put this distinction into the philosophical context of the times. When asked by Edward R. Murrow who held the patent to his vaccine, Salk replied, "Well, the people, I would say. There is no patent. Could you patent the sun?"[9]

In 1974 Harvard began systematically to take out patents previously dedicated to the public. Patents originating in Monsanto-funded laboratories were licensed to Monsanto on an exclusive basis, meaning that Monsanto had the right to develop and market products stemming from Harvard's research for 17 years, without competition. In late 1975, Harvard revised its patent policy to incorporate offically these changes in practice. For the first time, all faculty members, students and workers were obligated to report findings which "might be useful, patentable, or otherwise protectable, including potentially useful biological materials" to the University. Harvard retained the right to step in and file for the patent if the inventor did not do so in a timely manner. Inventors were encouraged to report their findings to the University before publication, since prospective licensees lose international protection of the exclusive licenses if no patent application has been made before publication.[10]

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[8] From "A Statement of Policy in Regard to Patents on Discoveries or Inventions Bearing on Health and Therapeutics," issued by Harvard University, October 23, 1959.

[9] Barry Werth, "The AIDS Windfall," New England Monthly, June 1988.

[10] From "A Statement of Policy in Regard to Patents and Copyrights as Adopted by the President and Fellows on November 3, 1975."

Harvard gave Monsanto the right to review all scientific papers relating to the Agreement before their submission to scientific journals and to delay their publication for 90 days while the company and university applied for patents on the contents of the paper. Prepublication review rights have become standard aspects of subsequent agreements between Harvard and industry. Besides slowing the publication of new information and its introduction into scientific debate, prepublication review rights change the flow of that information giving special access to an interested party. In the context of the commercial race to production, this translates into an advantage over competitors, known among industry scientists as "lead time." When industry sponsors research at the university, faculty researchers must strive to protect the sponsoring company's "lead time," a consideration that can conflict with his/her role as a scholar. Joyce Brinton, director of Harvard's Office for Patents, Copyrights and Licensing, recounted an anecdote of a researcher who, before leaving for a professional conference, asked the Patent office to file a patent application for the material he would present at the conference. In this case, Brinton and her associates worked through the night to complete the necessary paperwork, and the researcher made his presentation secure in the knowledge of patent protection.[11]

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[11] Interview with Joyce Brinton, director of the Office for Patents Copyrights and Licensing (PCL), Harvard University, March 18, 1988. PCL was established in 1977 to protect the commercial interests of corporate research sponsors and to lure greater amounts of corporate funding to the University. According to the Harvard University *Gazette* , (March 18, 1988), "Many Harvard faculty members are inventors and don't know it. It is David Stein [Technology Transfer Officer]'s job to tell them." Essentially, Stein and other PCL representatives alert faculty members to the possible profitability of their work. They meet with individual scientists and occasionally convene meetings with departments "just [to] talk about research" and estimate the possibilities of "practical application" of research findings, in Brinton's words. For the faculty-inventor, this could translate into personal financial gain. According to the University's royalty sharing policy, faculty-inventors are entitled to 35% of the first $50,000 in royalties from the net income that their inventions generate, and 20% of income exceeding $50,000. The inventor's department and the University benefit from the profits generated by the patent as well. After a patent application is filed, PCL canvasses industry for a licensee to develop the patent into a marketable product. Harvard publishes a catalogue of researchers and patents which it circulates to prospective corporate sponsors.

Upon agreement with Monsanto, Harvard undeniably implemented practices and adopted new policies whose sole purpose was to protect the interests of Monsanto and subsequent industry research sponsors. When asked why, for example, Monsanto had received prepublication review rights, Monsanto Vice President of Technology at the time, Monte C. Throdahl, replied, "We deserved something for the risk we were taking. [This] only makes sense from a business perspective."[12] But from a university's perspective, prepublication review rights and exclusive licensing arrangements undermine the strength of the university's mission as a facilitator of the "free and open exchange" of information. At the same time, these concessions serve the sponsoring industry's priorities uniquely; they establish a common, university-wide practice of withholding information from the public.

More than two years after the Agreement's expiration, Harvard and Monsanto still refuse to disclose the text of the Agreement, citing a stipulation in the charter that forbids its publication.[13] Ironically, however, it is Harvard not Monsanto that steadfastly refused to comment publicly on it. Monsanto's Throdahl was generally forthcoming in his responses to Harvard Watch's questions, and a fair amount of previously undisclosed information is now available due to our interview. Interviews of this sort do not substitute for public disclosure of the Agreement's charter, but they are an indication Harvard's about-face from advcating open discussion to imposing secrecy and stifling debate. Not a single Harvard administrator was willing to speak with Harvard Watch about the Agreement. Vice President and General Counsel, Daniel

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[12] Interview with Throdahl.

[13] Letter from Daniel Steiner, Vice President and General Counsel of Harvard University, to Harvard Watch, dated May 19, 1987.

Steiner, referred Harvard Watch to Stephen Atkinson, who at first seemed enthusiastic about straightening out our "misconception" about the Agreement, but who later refused to respond to our interview requests. If there is a moral to the Harvard-Monsanto story, it is that even the nation's preeminent university can shed its role as a facilitator of knowledge and conduct itself as a business partner with industry. Indeed, the Harvard-Monsanto Agreement marked a trend toward the university's corporatization, not the academization of the corporation. There is no evidence that Monsanto's contact with Harvard had the effect of making the company behave any more like a university.

Currently Harvard has signed agreements with many chemical and pharmaceutical companies. Both the wide extent and rapid proliferation of corporate sponsored biomedical research at Harvard are startling: by 1986, many of Harvard's faculty researchers were either consulting for or receiving research funding from the industry, and the University had entered research agreements with many major pharmaceutical and chemical companies in the country. It is impossible to say with certainty how many corporate sponsored research agreements are currently underway at Harvard, because the University does not publish this information. One indication of which companies sponsor research is to be found in the "Fund and Gift Supplement to the Financial Report." Approximately 32 companies, trade association and research institutes are currently giving monetary gifts to research laboratories and scientists at Harvard Medical School. They are:

> Abbott Laboratories, American Chemical Society, Biogen, Inc., Bristol-Myers, Council for Tobacco research, Du Pont, Eastman Kodak, Emtek Corporation, Genetic Technologies, GTE, Hoechst A.G., Hoffman-La Roche, Johnson and Johnson, Kaken Pharmaceutical, Laboratoires OM Societe Anonyme, Miles Laboratories, Monsanto, Pharmaceutical

Manufacturers Association, Pfizer Inc., R.J. Reynolds, Revlon, Sandoz, Schering-Plough, Shiseido, SmithKline Beckman, Smokeless Tobacco Research Council, Sterling, Stroh Brewery, Syntex Corporation, Union Carbide, Upjohn Company, Westwood Pharmaceuticals Inc.[14]

The classified status of research agreements poses specific problems to individuals who wish to investigate questions such as the existence of a prepublication review clause, the formal rights and responsibilities of the faculty researchers involved, the effect upon the recruitment of students and other researchers. This information is important in order to monitor the actual influence of corporate sponsors over the university, and equally, the University's commitment to its own standards of disclosure.

Certainly, the University's position regarding the proprietary rights of sponsors has evolved significantly from its position before the signing of the first Agreement. Harvard has increasingly aligned its own standards with those of its corporate sponsors, but what is unknown is the extent and precise nature of those changes. It would be impossible at the present time, for example, to survey the various procedural restrictions on open disclosure in all of Harvard's corporate sponsored research agreements, since only one of them has been publicly disclosed.

The secrecy of research contracts between the University and the sponsoring corporation has caused public officials chagrin. The case of the Massachusetts General Hospital (MGH)-Hoechst Agreement is pertinent. In 1981, Hoechst A.G., a West German pharmaceutical firm, signed the largest joint research agreement in history with Harvard-affiliate, Massachusetts General Hospital. In exchange for providing $70 million over ten years, the

[14] Compiled from "Fund and Gift Supplement to the Financial Report," 1986-1987, published by Harvard University.

construction of and equipment for a new microbiology department at MGH, Hoechst received many concessions (exclusive patent rights, on-site training of Hoechst scientists) similar to those found in the Harvard-Monsanto Agreement of 1974. The unique aspect of this agreement was Hoechst's West German base. Then-Congressman Albert Gore, Democrat from Tennessee, who was leading a congressional investigation into biotechnology at the time, questioned the appropriateness of such agreements. "How should we react to the fact that you've signed this exclusive licensing agreement with a foreign chemcial company," asked Congressman Gore of Dr. Ronald Lamont-Havers, director of Research at MGH, "in light of the fact that the American taxpayers are providing $25, $26 million to your institution... to produce products for Hoechst?" As a publicly built and maintained resource, argued Gore, the MGH was not Lamont-Havers' to give away. Lamont-Havers responded defensively, saying, "[That is a rather] inflammatory statement, if I may say so." Gore: "I view the agreement as inflammatory." Lamont-Havers: "Well, I don't think you've read it very carefully, anyway." Gore: "You haven't given it to me."

With universities increasingly collaborating with industry, it is doubtful that Harvard has made a more influential and far-reaching contribution to the academic community within the last half century than the Harvard-Monsanto Agreement. Yet it has been a contribution conceived in paradox. Harvard Watch asked Monsanto's Throdahl how the Harvard-Monsanto Agreement could be a "pathbreaker" and a model for subsequent agreements in view of the fact that the actual text of the Agreement has not been publicly disclosed. For in order to be both a pathbreaker and a model, the Agreement should plausibly have been reproducable not only by Harvard, in subsequent research agreements with corporations, and by Monsanto, but by other universities, as well. One would have expected that colleges and universities evaluate and

experiment with the Harvard-Monsanto model. Scholarly debate should have been a matter of course. Articles should have been written and studies conducted to establish the merits of certain provisions over others. Academic conferences should have been convened and the Harvard-Monsanto Agreement examined under the academic microscope. Harvard's negotiating innovation should have itself become the subject of scholarly inquiry.

But instead of generating debate, the Harvard-Monsanto Agreement ushered in secrecy. Both Harvard and Monsanto concealed their agreement as "proprietary information." As a business partner, Harvard agreed to undermine the academic creed. Secret negotiations, secret agreement implementation, the classified status of the agreement charters -- these have become the model for subsequent research agreements between Harvard and industry, and for other universities and industry as well.

In answer to Harvard Watch's question, Throdahl replied, "You got us there."

3. The New Classified Research

Harvard Watch sought information about the University's relationships with pharmaceutical and chemical companies from a wide variety of University sources, including University publications and department administrators and workers. The information requested reasonably fell into the category of "public" as it is characterized by University policy, government standards of disclosure regarding sponsored research at Harvard, and President Derek Bok in his most recent commentary on the subject of secrecy.[15]

Harvard Watch made repeated attempts to obtain information regarding the nature and the extent of Harvard's research agreements with the biomedical industry and was refused access to this information. Frequently, Administrators failed to respond to numerous telephone requests. For example, Stephen Atkinson, director of Harvard's Office of Technology Licensing,was called no less than twenty times over a period of one and one-half weeks for information about the number of corporations which have signed research agreements with Harvard -- information which falls into the public realm; Atkinson did not reply. Ironically, not a single member of a "Public Advisory Board," established pursuant to the Harvard-Monsanto Agreement of 1974 to protect the public's interest, replied to repeated requests for interviews. Harvard Watch concludes that:

• the public does not have direct access to any information regarding corporate sponsored research agreements. Harvard does not publish a list of its corporate sponsors, the purpose of the research, and principal investigators.

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[15] Derek Bok, "Reflections on Secrecy," supplement to the Harvard University *Gazette*, Novemeber 21, 1986.

• the University does not specifically enumerate the dollar amount of corporate sponsorship in any publication. There is no central repository or reliable and easily accessible source of information on corporate sponsored research. Harvard's "Financial Report" lumps the income from corporate sponso ship into a statistical column labeled "Other." A more precise figure is impossibl to derive.

• Harvard obstructs the public's access to certain information, directly contradicting the University's regulations governing disclosure. First, the Medical School's Office of Technology Licensing and the University's Office of Patents, Copyrights and Licensing will not release a list of all corporate sponsored research projects on a by-company basis, because, staff people say, it would require "too much work." Therefore, it is difficult to gather information about the total amount of corporate sponsored research or draw conclusions about the relative extent of corporate sponsorship. Second, in order to guarantee complete disclosure, the seeker of information is instructed to provide the office the names of the sponsoring corporation, the principal investigator, and the University account number. Since this is nearly all the information the University will provide about corporate sponsored research anyway, it is difficult to imagine the utility of the office.

Harvard also routinely refuses to make public other kinds of information that may be of great importance. The recent case of Scheffer C. G. Tseng and the illegal experiments he performed on hundreds of people at Harvard-affiliate Massachusetts Eye and Ear Infirmary illustrates this practice. Between 1984 and 1986, Scheffer Tseng was a research fellow at Mass. Eye and Ear testing a

treatment he had developed several years earlier for *keratoconjunctivitis sicca* , commonly known as dry-eye syndrome. Ostensibly, his experiments with Vitamin A were very promising. According to a scientific article he published in June1985, "After treatment, all patients demonstrated clinical improvements in symptoms." Tseng published four more articles between 1985 and 1987 which extolled the effectiveness of his treatment.

Then in 1988, two years after Tseng had left Harvard for the University of Miami Medical School, the Boston Globe reported that Tseng had misrepresented his data and profited significantly from it.[16] Tseng's initial public announcement of the effectiveness of his treatment grossly misrepresented its actual performance. The Globe also revealed that Tseng revised his research protocol without informing Harvard, administered his treatment illegally, and even surrepticiously required his patients to self-administer unmarked substances. All of these constitute grave ethical and academic violations. Why did he do it? Tseng was one of the founders of and a stockholder in Spectra Pharmaceutical Services, Inc., a firm that produced his Vitamin A product. Tseng earned about $1 million from stock sales.

Research fellows like Tseng have faculty advisors who oversee their work. Tseng's was Kenneth Kenyon, associate chief of ophthalmology at Mass. Eye and Ear. The Globe article reports that instead of overseeing Tseng's work, Kenyon ignored numerous reports from nursing staff that Tseng abused patients. Kenyon also ignored Tseng's obvious misuse of federal grant money, since the National Institutes of Health (NIH) grant which funded Tseng's research limited the number of human subjects to 50, while Tseng had augmented that number to over three hundred. On at least one occasion,

[16] Peter Gosselin, "Flawed study helps Doctors Profit on Drug," *Boston Globe*, October 19, 1988, p. 1.

Kenyon allegedly administered to a patient a substance that was not approved by the Federal Drug Administration to alter the results of Tseng's experiments. Kenyon also held stock in Spectra Pharmaceutical Services, Inc.. He reportedly earned over $300,000 from the sale of his stock following the publication of Tseng's first article.

Harvard University has known about these abuses since Spring, 1988, and in all likelihood, earlier still, but did not disclose them publicly. Mass. Eye and Ear convened an academic review committee to investigate charges of misconduct on Tseng's part. They submitted their report to Harvard Medical School Dean, Daniel C. Tosteson, whose committee in turn issued a report in 1987. The report languished and Tseng continued his experiments elsewhere. A version of it was only published the day the Globe ran its first article on the case. Many questions arise regarding Harvard's handling of the Tseng case.

Harvard regularly publicizes the scientific accomplishments of its faculty, with no obvious social benefit. Why did Harvard refuse to reveal the contents of its investigative report, which had obvious and immediate social value? Why does Harvard continue to withhold information regarding Tseng's wrongdoing at the present time? Harvard Watch asked Medical School Dean Daniel Tosteson these questions and others. A full transcript of our conversation is included below. Tosteson's answers came by way of the Harvard News Office.

Harvard Watch: Did Dean Tosteson's committee notify the NIH of its findings, whose funds Tseng was illegally misusing?

Tosteson: No comment.

Harvard Watch: Did Harvard publicly refute Tseng's scientific articles?

Tosteson: No comment.

Harvard Watch: Did Harvard notify Johns Hopkins University (where Tseng did his initial experiments before 1984) or the University of Miami (where Tseng went after leaving Harvard in 1986) about its findings?

Tosteson: No comment.

Harvard Watch: Has Harvard followed-up on the health and psychological well-being of Tseng's former patients?

Tosteson: No comment.[17]

Indeed what responsibility to the public did Tosteson have to disclose his knowledge? Why did Harvard fail to expose the public health risks associated with its own researchers work?

Though Dean Tosteson would not comment to Harvard Watch on these questions, it is instructive to examine what Tosteson has said about the Medical School's societal mission in another context:

> "[M]edical schools are guided by three objectives: 1. They seek to improve medical practice. 2. They wish to pursue all promising opportunities to discover the source and cure of disease. 3. They strive to maintain research integrity by discouraging their investigators from accepting secrecy requirements or devoting too much time to commercial pursuits."[18]

Tosteson wrote the above in defense of the Medical School's recent plan to create a venture capital fund with which to invest in the commercialization of faculty's biomedical research projects. However, each of the three points Tosteson makes are equally applicable to cases of impropriety of its researchers. If Harvard Medical School feels it must pursue "all promising opportunities... to cure disease," then Harvard certainly has an obligation to

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17 Interview with Peter Costa, Harvard News Office and spokesman for Dean Tosteson, November 7, 1988.

18 Daniel C. Tosteson, Letter to the Editor, *New York Times*, October 3, 1988.

protect the public from abuse, manipulation and physical and psychological damage caused by its own researchers.

Yet the Medical School obviously did not act with the same commitment to the public as it has to commercialize its faculty's research. Tosteson did not release his knowledge or the academic review committee's report to the public. If the Tseng case illustrates anything at all, it is that public access to information like the report of Harvard's review committee and Tosteson's report is essential. The Globe's article appeared fully two years after the facts of the case were first known to individuals affilitated with Harvard; yet by all accounts, they did not make their knowledge publicly available. Harvard officials observe silence even to this day.

4. Conclusion

Harvard's failure to disclose publicly important information about corporate sponsored biomedical research invites comparison to precisely a situation that former Harvard President James B. Conant aimed to prevent. At the close of World War II, Conant forbade the Harvard faculty to participate in classified government research.[19] He reasoned that both the scholarly community and the greater public benefitted when scholars were able to exchange and publish the results of their research freely and when they were able to comment about it in public freely. Classified research is antithetical to these values because it permits the research sponsor, in this case certain branches of the government, to withhold from the public information and knowledge discovered at the university.

The comparison of corporate sponsored research with classified government research is not a perfect one. Researchers may publish the results of their research when it is funded by corporations. But the fundamental difference between the two sources of research funding, and the basis of the comparison, is the special responsibility corporate sponsorship places on the university as an institution. In accepting corporate sponsorship, the university steps into the role of a business partner and assumes the responsibility to censor itself. Ironically, academic standards stand in the way of further and more extensive partnership with industry, which makes no pretensions toward openness and public disclosure. In Harvard's case, ever closer ties with the biomedical industry have given rise to amendments to those standards, giving

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19 "Report of the President of Harvard University," 1945-1946, pp. 13-14. President Conant makes reference to his interdiction of classified research again in his "Report," 1950-1951, in which he writes, "No secret research is being done here at the present time," p. 8.

the sponsoring corporation influence over the publication of academic articles and papers. Increasingly, corporate sponsored research agreements legitimize infringements on Harvard's disclosure standards and endanger the integrity of the University's public safeguards.

These amendments have been initiated from the top down. Harvard's Administration paved the way to ever closer ties with industry by trading off fundamental academic standards and a commitment to the dissemination of knowledge for the financial benefits of a partnership with industry. As Vice President and General Counsel Daniel Steiner remarked in congessional testimony, Harvard stood to gain financially the "apple." But Harvard's Administrators have acknowledged the pitfalls of this trade-off publicly as well. President Bok notes the dangers specific to the new academic ethos of "technology transfer" (i.e. university collaboration with industry) when he writes, "[T]he newfound concern with technology transfer is disturbing not only because it could alter the practice of science in the university but also because it threatens the central values and ideals of academic research."[20] Vice President of Government, Community and Public Affairs John Shattuck acknowledged that the current network of relationships between faculty and industry "is fraught with danger."[21] Unethical researchers such as Scheffer C. G. Tseng and compromised overseers such as Dr. Kenneth Kenyon are not only the causes of serious problems but they are also symptomatic of the larger and more widespread problem: institutional secrecy which has accompanied the University's ever closer relationship with industry. If there is a lesson to be learned in the Tseng case, it is that Harvard University, by virtue of not

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[20] Derek Bok, Beyond the Ivory Tower, Harvard University Press, 1982, p. 142.

[21] Andrew J. Bates, "Shattuck Criticizes Bush for Attacks on ACLU," Harvard Crimson, October 6, 1988.

disclosing information, has played a part in the perpetuation of the problem and the obstruction of its resolution.

What should Harvard do now? Harvard should immediately and publicly disclose the review committees' conclusions regarding the Tseng case. Harvard should also produce the evidence on which those committees based their conclusions. Second, Harvard should take steps to prevent a similar case of conflict of interest by publicly disclosing the outside affiliations of all Harvard researchers. Harvard researchers should not benefit financially from stock holdings in companies that develop the products of their scientific research. Nor should business partners oversee one another's scientific research. The key to implementing this recommendation is public disclosure of extramural affiliations, be they membership on scientific advisory boards, consulting relationships or corporate board membership. A more in-depth treatment of recommendations is to be found in the following section of this report. If there is a unifying theme, however, it is that Harvard must take an active role in disclosing information. At the present time, Harvard actively withholds information with deplorable but preventable consequences.

5. Harvard's Top 4 Secrets and Recommendations for Their Disclosure

Secret #1. The members and conclusions of academic review committees and all other committees that investigate ethical misconduct.

Recommendation #1. Harvard should regularly and promptly make this information available to the public. The information that comes out of academic and misconduct committees is immediately significant to the public. The case of Scheffer C. G. Tseng at the Massachusetts Eye and Ear Infirmary is illustrative. Had Harvard's academic review committee publicly disclosed the results of its investigation in 1986, perhaps hundreds of individuals would not have been put in danger by the unethical doctor.

It may be objected that such disclosure might wrongly damage the reputation of university researchers, doctors and other faculty members. This objection is flawed since only the conclusions of the committee would be published, and only those of researchers found to be culpable. Those conclusions represent the opinions of qualified peer reviewers. If they conclude that a faculty member or university affiliate is behaving unethically, then the public ought to be given the same access to that information as University administrators. The question of reputation is not an appropriate one, since the review committee has presumably established unethical behavior in fact. This is of direct and obvious public concern.

Disclosure would protect the public by the timely release of valuable information. At the present time, the Dean may release information to the public on an ad hoc basis, but is under no obligation to do so. Procedure Six of Harvard's "Procedures for Responding to Allegations of Misconduct in

Research" specifies, "The Dean shall then take whatever action he or she considers appropriate." Medical School Dean Tosteson's recent withholding of crucial information is an example of the pitfalls of arbitrary discretion.

In another example of review committee secrecy, the Harvard-Monsanto Agreement of 1974 reportedly created a "public advisory board" to oversee the research and protect the public's interest.[22] It is reasonable that such a Board, with the responsibility to protect the public's interest, be accountable to that public. However, of the four surviving individuals appointed to serve on the Board, Harvard Watch made repeated attempts to interview three, and not one of them responded to interview requests.[23] Further, there is no public record, as far as Harvard Watch is aware, of Board meetings or discussions during the twelve years of the Agreement. Since the Agreement itself was not publicly disclosed, no outside individual had information enough to question or determine whether the Board was doing its job.

Academic review committees provide a unique opportunity for evaluation and fact finding on specific matters of public concern. The public must have ready access to information of this sort in order to make use of it, and the University, for is part, has a responsibility to provide it.

Secret #2. The text of research agreements between Harvard and the sponsoring company.

Recommendation #2. Harvard should publish the texts of its research agreements with private industry. Many questions arise when Harvard works

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[22] Barbara J. Culliton, "Harvard and Monsanto: The $23 Million Alliance," *Science*, Volume 195, 25 February, 1977, p. 762.

[23] The single surviving Board member who was not contacted by Harvard Watch is Sir David Philips, member of the American Academy of the Sciences and professor of chemistry, Oxford, England. He was not contacted because of the excessive costs of attempting to do so.

jointly with a corporation: On what terms may researchers and students be recruited to work on the sponsored project? What is the nature of contact between the laboratories and researchers of the sponsoring company and Harvard's laboratories and researchers? Do company researchers work at Harvard? If so, in what capacity? Answers to these questions are essential if the University is to function as a legitimate and independent source of knowledge in society.

It may be the case that some information contained in these agreements is such that its disclosure does not significantly add to the public's understanding of the nature and extent of the company's influence at the University while its secrecy is necessary to the corporate sponsor. Any exceptions to public disclosure should be clearly specified in Harvard's disclosure policies and not be left to ad hoc decisions or an Administrator's discretion. Moreover, withholding of information should be minimal. As a rule, research agreements should be made public, and if it is determined that public disclosure of research agreements is not acceptable to the sponsoring corporation, then by Harvard's own standards of disclosure, such a research agreement is not in the University's interest.

Secret #3. Extramural affiliations and commitments of Harvard faculty.

Recommendation #3. Harvard University should compile and publish a record of its faculty's extramural affiliations and commitments. Intellectuals and university researchers have a special advisory function in society. The general public, the government and private corporations rely upon them for their professional and independent opinions and therefore provide them with unique opportunities to inform and influence public policy. University faculty often are

called upon to give expert testimony at congressional hearings. They are often appointed to advisory postions in governmental administrations. They often publish articles in popular magazines and newspapers. Biomedical corporations also rely upon researchers as consultants and as members of scientific advisory boards. Many Harvard faculty consult for companies, sit on scientific advisory boards, and receive research funding from private corporations.[24]

It is not unusual that a faculty member's extramural affiliations place him or her in a conflict of interest. Extramural affiliations can influence the content of the testimony a faculty member gives to Congress. Extramural affiliations can influence the professional judgments of overseers and members of academic review committees. The case of Scheffer C. G. Tseng is only one disclosed example of the second. The deplorable role of Dr. Kenneth Kenyon, who was Tseng's faculty overseer as well as a beneficiary of Tseng's biotechnology company, might have been averted if his shareholdings had been publicly disclosed. This knowledge is crucial both to the faculty and to the public, in whose confidence and trust faculty act. The University administration should take the lead in preventing potential conflicts of interest. The public disclosure of faculty's extramural affiliations would help the public as well as the faculty to avoid the dangers resulting from conflicts of interest and misuse of federal grants.

Secret #4. The name of each company that sponsors research at Harvard, the amount in dollars of their sponsorship, the principal

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[24] For an account of the issues involved when faculty have outside affiliations and for aggregate data documenting those affiliations of Harvard's faculty, see "Scholars, Inc.," Harvard Watch, November 16, 1988.

investigators who benefit from the sponsorship, and a detailed explanation of the purpose of the research.

Recommendation #4. Harvard should make this information publicly available at a central location and in a comprehensive form. Harvard should publish a volume describing every corporate sponsorship.

This recommendation is mainly an appeal to enforce and enhance Harvard's own existing policy, as laid out in "Principles Governing Research Conducted Within the Faculty of Arts and Sciences," with one exception. Harvard Watch calls for the University to publish a detailed explanation of the research. Currently, Harvard University will only furnish the public with a research title, which does not usually exceed five words. Often they are as crytic as they are provocative; for example: "Molecular basis for Pulmonary surfactant secretion by Type II pneumonocytes;" and "Physiopathology of normal and activated macrophages." The public cannot be expected to glean an understanding of the research from these miserly titles. Yet individuals might wish to inquire what research Harvard is performing under sponsorship of the cigarette industry, and their investigation would probably be stymied by the brevity of the above research titles, both of which are taken from projects funded by the Council for Tobacco Research.[25] For "public disclosure" to be a publicly useful policy, the University must disclose a detailed explanation and description of the purpose of the research, stating its aims and foreseeable commercial application.

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[25] "Fund and Gift Supplement," Harvard University, 1985-1986.